United States Court of Appeals

for the Second Circuit

APPELLANT'S REPLY BRIEF

74-1738

ORIGINAL

To be argued by
MILTON A. BASS

In The

United States Court of Appeals

For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION, and SOLGAR, CO., INC.,

Plaintiffs-Appellants,

vs.

CASPER W. WEINBERGER, Secretary of Health Education and Welfare and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

On Appeal from the United States District Court for the Southern District of New York.

REPLY BRIEF FOR APPELLANTS

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UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 74-1738

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THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs-Appellants

-v-

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

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REPLY BRIEF OF PLAINTIFFS-APPELLANTS

Introduction

Plaintiffs-appellants respectfully submit this Reply Brief in response to the Brief filed herein by Defendants-Appellees.

POINT I

THIS COURT HAS ALREADY INVALIDATED THE RATIONALE UNDER WHICH APPELLEES CLASSIFIED VITAMINS A AND D AS "DRUGS" HEREIN

Appellees concede (Brief p. 22) that the imposition

of prescription requirements for vitamin A and D products necessarily requires that these items be first considered as "drugs" within the meaning of the Federal, Food, Drug, and Cosmetic Act. As noted in Appellants' Main Brief, (pages 61-63), the identical issue with respect to the propriety of an attempted drug definition was presented to this Court for decision in National Nutritional Foods Association and Solgar Co., Inc. v. Food and Drug Administration (2nd Cir. 73-2129, et al., Slip Op, August 15, 1974) (hereafter, NNFA v. FDA). Despite the decision in that case, adverse to the FDA position, Appellees seek herein to relitigate the same legal and factual issues already decided by this Court in a proceeding involving the very same parties.

A. In Treating Vitamin A and D As Drugs, The Agency Expressly Relied On The Record Which Was Before This Court in NNFA vs. FDA, Supra.

The Statement of Policy herein attempts to treat vitamin A and D products in excess of 10,000 I.U. and 400 I.U. respectively as "drugs" under the Federal, Food, Drug, and Cosmetic Act. The original agency proposal on December 14, 1972 with respect to prescription levels for vitamins A and D made no attempt to set forth any rationale for the classification as "drugs" of these products which have long been sold as dietary

food supplements in excess of the specified potency levels. On January 19, 1973, however, the agency published in the Federal Register a wholly separate Tentative Final Order which was the end-product of more than a decade of administrative proceedings with respect to all vitamin products. No issue had ever been raised in those proceedings as to "drug" status of vitamin products. Nevertheless, the proposal contained a specific provision classifying as "drugs" all vitamin products in excess of specified potencies. See 38 F.R. 2150 (Jan. 19, 1973) 21 C.F.R. §125.1(h)

Objections were filed with the agency as to both the vitamin A and D proposal and the general vitamin drug definition along virtually identical lines. In each case affected members of the public noted (along with other objections) that there was no basis or authority under the Federal Food, Drug, and Cosmetic Act for arbitrarily classifying dietary food supplements as "drugs." */ Finally, on August 2, 1973, the agency promulgated both the general vitamin regulations, including the purported drug definition, as well as the instant vitamin A and D Statement

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*/ The suggestion in Appellees' Brief (footnotes on pages 22 and 29) of a supposed contradiction on the part of Appellants is misplaced. Appellants merely noted in their Main Brief, that even if the products were deemed drugs, they could not be classified "prescription drugs."

of Policy.

On that date the agency advanced for the first time the rationale that vitamin products could be considered "drugs" merely because they were sold in quantities exceeding the U.S. RDA's.* The agency rationale was comprised of two parts. First, the agency saw no food or nutritional purpose for vitamin products beyond the conservative levels set forth in the vitamin regulations. Secondly, the agency reasoned, that in the absence of such a nutritional purpose, the products involved were appropriate only for therapeutic purposes and thus could be classified as "drugs." See 38 F.R. 20710,col.2 (Aug.2, 1974). Thus, despite the fact that the products in question were being sold as dietary supplements the agency sought to impute a therapeutic intent behind their sale and thus provide the basis for drug classification.

In response to similar objections received as to "drug status" with the instant Statement of Policy, the comments accompanying the final agency action herein expressly relied on the general vitamin regulations as support for "drug" classification and advanced the identical theory as to vitamins A and D:

> "The question regarding whether a vitamin is a food or drug generated considerable discussion. The tentative and final orders promulgating §§ 80.1, 125.1, and 125.3 (21 CFR 80.1, 125.1 and 125.3), published in

*/ Recommended Daily Allowances.

the January 19, 1973 Federal Register (38 FR 2143, 2152) and elsewhere in this issue of the Federal Register discuss this matter in detail. */ (JA 32a Col. 3)

All aspects of the agency's rationale as to drug classification were vigorously disputed by Appellants herein and other petitioners before this Court upon review of the general vitamin regulations in NNFA v. FDA, supra. It was noted that the record before the Court did not support a finding of no nutritional purpose for vitamins at levels above those approved by the FDA. Moreover, it was pointed out that the definition was in any event contrary to the statutory definition cited by the agency. (§201(g)(1)(B) of the Act) [21 U.S.C. §321(g)(1)(B)]. There can be no question but that the identical legal and factual questions are also present in the instant case.

B. Listing of Vitamin A and D In The United States Pharmacopeia Does Not Classify Such Products As Drugs.

The District Court opinion herein allowed the agency's drug classification without any explanation other than a quotation of the relevant statute. (JA 32a) Judge Friendly's opinion in

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*/ The quotation of this paragraph in Appellees' Brief (pp. 24-25) omits this introductory portion which shows the reliance herein on the record of the general vitamin regulations.

NNFA vs. FDA, supra, takes note of this failure to deal with the drug issue. The FDA claimed that Judge Frankel's decision herein had already determined the validity of the agency's drug definition. The Court noted, however:

> "The decision that vitamins A and D in dosages above the given level were 'drugs' at all was reached in the first opinion with a degree of ease obviously dictated by Judge Frankel's view that they had properly been placed in the even more restrictive prescription category, and was reached in the second opinion without explicit treatment." Id. at 5250-5251, footnote no. 33.

As noted above, the agency's expressed rationale for drug classification is based on the theory that these products are purportedly "intended for use in diagnosis, cure, mitigation, treatment or prevention of disease" within the meaning of §201(g)(1)(B) of the Act [21 U.S.C. §321(g)(1)(B)].

Despite the agency's prior express reliance on §201(g)(1)(B), Appellees claim in their Brief that these products can also be classified as "drugs" under §201(g)(1)(A) because vitamins A and D are listed in the United States Pharmacopeia and National Formulary. It is troublesome that Appellees should persist in advancing this rationale, particularly since it has already been rejected by this Court. It is well established that the courts do not accept counsel's post hoc rationalizations for

agency action. Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962); U.S. ex rel Checkman v. Laird, 469 F.2d 773 at 780 (2d Cir. 1972); NLRB v. Clark, 468 F.2d 459, 467 (5th Cir. 1972); NLRB v. Groendyke Transport, Inc., 372 F.2d 137, 141 (10th Cir. 1967); SEC v. Chenery Corp., 318 U.S. 80, 87 (1943).

In any event, mere listing in the United States Pharmacopeia does not automatically determine drug status under the Act. In Amp Incorporated v. Gardner, 275 F.Supp. 410 (SDNY 1967), aff'd 389 F.2d 825 (2d Cir. 1968), for example, the court rejected the FDA's contention that a product was a drug (rather than a device) merely because it was listed in the United States Pharmacopeia. In addition, the approach to drug classification advanced by Appellees would clearly lead to absurd results. Water is listed in the United States Pharmacopeia immediately after vitamin A capsules (JA 296a) along with olive oil (JA 298a), common salt (sodium chloride) (JA 299a), and peanut oil (JA 298a). It is obvious that Congress never intended that these products should be considered as drugs when they are not used for a therapeutic purpose merely because they are listed in one of the compendia. .

The agency attempted to present the same argument with respect to vitamin products as to listing in the official

compendium in the recently decided case of NNFA vs. FDA, supra. This court emphatically rejected such an approach:

> "Although the findings on which the FDA apparently sought to rest §125.1(h) were evidently based on subdivision B of §201 (g)(1), see 38 F.R. 20170, ¶12 (1973); cf. id. at 20715, ¶44; id. at 20735, ¶11, government counsel now suggest that they could properly have been based on subdivision (A), since all the vitamins and presumably all the minerals with which we are here concerned are recognized in the official United States Pharmacopoeia or the official National Formulary. If this argument be seriously advanced, a sufficient answer is the statement in Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962), that '[t]he courts may not accept appellate counsel's post hoc rationalizations for agency action.' Moreover, the argument would prove too much, for it would lead to the conclusion that all vitamin and mineral preparations even within the limits are drugs--a position which would run counter to the regulations."
> NNFA v. FDA, supra, at 5251-5252

C. This Court Has Clearly Ruled Against Appellees' Primary Rationale For Drug Classification.

The primary rationale advanced by Appellees is equally invalid under §201(g)(1)(B). An article is considered a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals." 21 U.S.C. §321(g)(1)(B). Under long-established case law the intent of the seller is the key to determining whether the product is deemed a drug for the purpose of the act. Therefore, even a

common food product could be considered a drug under the statute if the seller made therapeutic claims for his product. In this way the drug enforcement provision of the statute can be used to protect the public from fraudulent sale of worthless "drugs." All of the cases cited on page 25 of Appellees' Brief involved situations where such therapeutic claims were in fact made. In the absence of therapeutic claims there can be no basis for classifying food products as drugs.

The record before this court in connection with the general vitamin regulations clearly showed that the RDA's would not necessarily satisfy all of the nutritional needs of all individuals. In addition, it was shown that the RDA's are based on concepts which exclude certain categories of nutritional needs and ignore widespread views as to "optimal levels of nutrition." Moreover, such record made it clear that the statistical basis for the development of the RDA's was far from perfect and complete. There is, therefore, no factual basis for the FDA's first premise as to lack of nutritional purpose.

It should also be noted that at no point in either the instant case or in the proceedings connected with the general vitamin regulations was there any evidence or indication of any therapeutic purpose for vitamins A and D in potencies exceeding 10,000 I.U. and 400 I.U. respectively. */ Even if the FDA's

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*/ General questions as to therapeutic purpose for all vitamins are now being considered by an FDA-sponsored panel.

claim of no nutritional purpose for vitamins A and D above the specified levels were to be accepted, the mere absence of nutritional purpose is not sufficient to convert honestly labeled food products into drugs in the absence of either an actual or intended therapeutic purpose. All of these factors were decisively ruled upon by this court in NNFA vs. FDA, supra:

> "Petitioners also object, both as a matter of statutory authority and as a question of substantial evidence, to §125.1(h), providing, with certain exceptions intended to conform to the standard of identity exemptions in §80.1(e), supra, that preparations containing more than the upper limits of the U.S. RDA per serving are drugs. This would implicate the many provisions of subchapter V of the Food, Drug and Cosmetic Act, including the more elaborate label requirements of §502, 21 U.S.C. §352, and, potentially, the burdensome provisions of §505, 21 U.S.C. §355, for approval of 'new drugs'; would involve petitioners in an elaborate investigation now being conducted by the FDA into the composition, labeling and sale of over-the-counter drugs, including '[v]itamin-mineral products,' 21 C.F.R. §130.301(b)(8), with the possible result that their products could be sold only on prescription or under other limiting conditions, id. §130.301(a)(5)(i);..." NNFA vs. FDA, supra, at 5249-5250
>
> * * *
>
> "The FDA's decision to handle as drugs all vitamin and mineral products in excess of the upper limits of the U.S. RDA's rested essentially on the thought expressed in paragraph 12 of the preamble to Part 125, 38 F.R.20710

(1973): 'The hearing record discloses no known food or nutrition use of nutrients at such high levels, and no such uses were shown in the exceptions.' We believe that this mischaracterizes the record. As will emerge more fully in the next section of the opinion, dealing with the RDA's as a basis for the upper limits in the standards of identity, a significant number of persons have indisputable nutritional need for potencies exceeding the upper limits; in particular, and by no means exclusively, this includes the large number of women taking oral contraceptives. In light of this, it cannot be said even as an objective matter that a given bottle of pills, each containing more than the upper limit of one or more nutrients, is not being used for nutritional purposes.

A fortiori it follows that the vendor of such a product can in good faith intend it for nontherapeutic use. Section 201(g)(1)(B) makes the vendor's intent the crucial element in the definition of 'drug' here at issue, see also S. Rep. No. 361, supra, in Dunn at 240, and the cases consistently have read that language for its plain meaning." NNFA vs. FDA, supra, at 5252-5253

"While we agree that a factfinder should be free to pierce all a manufacturer's subjective claims of intent and even his misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people. We therefore hold that §125.1(h) is invalid." */ NNFA vs. FDA, supra, at 5253

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*/ "While we thus reach this holding as a question of insufficient evidence, we must agree with petitioners that an

> administrative interpretation in such direct conflict with a legislative definition might also be invalidated on the ground of exceeding the agency's statutory authority." (NNFA v. FDA, footnote at 5253).

It is apparent that this Court has expressly overruled the "drug" rationale upon which the instant Statement of Policy was based. The attempt to limit vitamin A and D products sold as dietary supplements to prescription sale is therefore invalid and beyond the scope of the agency's authority under the statute. On the basis of the foregoing, it is respectfully submitted that the District Court erred and that the Statement of Policy concerning vitamins A and D should be held invalid.

D. The Non-Drug Status of Vitamin A And D Will Not Prevent The Agency From Properly Protecting The Public

A constant theme in Appellees' Brief is the agency's assertion that we are here discussing very dangerous products. Appellants respectfully submit that the existing classification of vitamins A and D as foods does not interfere with legitimate agency efforts to protect the public from unsafe products. Under §402(a)(1) of the Act [21 U.S.C. §342(a)(1)] any food which is injurious to health is deemed "adulterated" and therefore subject

to the enforcement provisions of the Act. If, in fact, any dangerous food product is sold the agency has full authority to protect the public.

POINT II

APPELLEES HAVE FAILED TO SHOW THAT THE STATEMENT OF POLICY COMPLIES WITH THE REQUIREMENTS OF THE PRESCRIPTION STATUTE

Section 503(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §353(b)(1)(B)] clearly lays down the prerequisites to classification as a prescription drug. See Appellants' Main Brief, pages 31-39. These requirements are detailed and precise. In terms of compliance with the statutory requirements, the agency was presented with one simple question: Can vitamins A and D in potencies in excess of 10,000 I.U. and 400 I.U. respectively be used safely without the supervision of a physician? This essential criterion derived from the express language of the statute and the undisputed legislative history was totally disregarded by the agency, thus necessarily invalidating the Statement of Policy.

Once again, by way of post hoc rationalization, Appellees' Brief (page 27) suggests that findings as to these requirements are "implicit" in the promulgation of the Statement

of Policy. If Appellees' view is correct, then judicial review of the agency's Statement of Policy is an empty formality. Appellees would have this Court "implicitly" equate the agency's interpretive statement with factual adjudication.

The essential point, totally ignored in Appellees' Brief, is that the prescription statute does not, and was never intended to, apply abuse or misuse of otherwise safe products. */ Under Appellees' rationale almost every product, beginning with aspirin, would have to be placed on a prescription basis because adverse effects, including death, would result from abuse or misuse.

Appellees' assertion (Brief, pp. 29-30) that the agency properly chose, in its discretion, among various alternatives in deciding to impose prescription status, points out a basic error in the agency's premise and approach. No such broad discretion is vested in the agency. **/ The legislative history, as

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*/ Appellees' purported factual distinction of the Decholin case (Appellees' Brief, p.32) is totally misplaced and irrelevant. Appellants cite Decholin, not for its facts, but for the legal principles discussed in great detail and the comprehensive presentation and analysis of the legislative history. See Appellants' Main Brief, pp. 15-16. The Decholin analysis clearly shows that "abuse" of a product is not a basis for imposing prescription requirements.

**/ The situation here is totally different from regulations dealing with standards of identity where the statute (21 U.S.C. §341) under a broad express grant of authority allows the agency to make such policy choices. The decision in NNFA v. FDA, supra, dealing with such regulations, contrary to Appellees' claims (Brief, fn. pp. 29-30), is of no relevance in this respect.

discussed in Appellants' Main Brief (pp. 12-18, 31-39), shows that Congress was very much concerned that the agency might try to remove products from the market by resorting to prescription requirements. Consequently, a very strict and precise prescription statute was drawn to limit such status to products which could not be used safely "except" under the supervision of a physician. Where this requirement is not met, as in the instant case, a prescription status cannot be imposed by the agency.

On the other hand, the statute is equally precise in prescribing the remedy to be used in order to protect against drug product overdosage:

> §502 [21 U.S.C. §352]
>
> "A drug or device shall be deemed to be misbranded --
>
> (f) Unless its labeling bears...(2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." (emphasis added)

It is not Appellants who "suggest" recourse to the above section, as opposed to the prescription statute. */ The

*/ Appellees' post hoc suggestion (Br. pp. 29-30) that the agency made a choice between such options, misrepresents the record herein. There is absolutely no indication in the Commissioner's statements in the Federal Register (JA 32a-37a) that any consideration was ever given to this question. This is particularly significant in light of the fact that the agency routinely relies on such label warnings with respect to other products which are even more seriously subject to misuse. See discussion relating to aspirin in Appellees' Main Brief, pp. 13-14.

statutory scheme explicitly determines that if a product is a drug at all, prescriptions are not required when safe use is possible without supervision of a physician while protection against overdosage is to be provided by way of appropriate labeling. The agency's adoption of an "abuse" rationale for prescription classification has no basis in the statutory definition. It is respectfully submitted that the non-statutory basis for the vitamin A and D prescription requirements invalidates the instant Statement of Policy as a matter of law.

POINT III

THE AGENCY POSITION HEREIN FRUSTRATES THE EXPRESS LEGISLATIVE INTENT BEHIND THE PRESCRIPTION STATUTE

The crucial question in connection with the implementation of the legislative intent behind the prescription statute is the nature of the authority granted to the agency under §701(a) of the Act. [21 U.S.C. §371(a)]. Under Appellants' view, the expressed congressional intent of requiring a full factual judicial scrutiny as to prescription status is preserved because §701(a) authorizes only interpretive regulations and statements of policy which are subject to full factual challenge in either enforcement proceedings or by way of a declaratory judgment action

in a district court. On the other hand, Appellees' view of §701(a) as a vehicle which can be used to promulgate binding prescription regulations, subject to only the narrowest judicial review, defeats the express legislative intent with respect to the imposition of prescription status.

In enacting the prescription statute, Congress clearly understood §701(a) to be limited to interpretive regulations. The Senate Report, quoted so extensively by Appellees, (Brief pp. 13-14) describes such authority as "interpretive" at least four times and also expressly notes:

> "The Administrator can exercise the authority he has under §701(a) of the Federal Food, Drug, and Cosmetic Act to issue interpretive regulations." (emphasis added) (JA 286a)

The long-established legislative and case-law distinctions between interpretive and substantive regulations were extensively set forth in Appellants' Main Brief (pp. 19-29) and basically ignored in Appellees' Brief. Under Appellees' perception of §701(a), the enactment of the prescription statute was superfluous. As noted by the District Court (JA 387a, n.3) prior to its enactment, there already was a §701(a) interpretive regulation which provided virtually the identical standard now found in the statute. See 21 C.F.R. §1.106(b)(1), (b)(2)(ii) (1949). The true purpose of the prescription statute as enacted, however, was

to incorporate into the statute and thus give the force and effect of law to what had previously been only an interpretive regulation. During the debates, it was noted:

> "Mr. Bennett: Mr. Chairman, the effect of the O'Hara Amendment is relatively simple. What it does is to legalize the regulations under which the Food and Drug Administration has been operating in this field for a period of years." (emphasis added) (JA 244a)

Even more important, however, is the fact that Appellees' Brief simply bypasses the legislative intent of the Federal Food, Drug, and Cosmetic Act itself. Surely, the nature of §701(a) regulations cannot be determined without reference to the legislative history of the very section in question. At the risk of being repetitious, Appellants respectfully note once again the definitive and dispositive language of the House Report showing the intent of Congress in establishing the regulatory authority under the Act:

> "In the case of regulations the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given." (See fuller quotation and citation at pp. 41-42 of Appellants' Main Brief).

It is therefore clear from the legislative history that a regulation under §701(a), which is promulgated without a public hearing (such as the instant Statement of Policy), is only interpretive and the violation of such a regulation does not per se

constitute an offense. This is in accord with the long recognized nature of interpretive regulations as allowing litigants a full opportunity to develop the facts relative to the validity of such regulation. Indeed, the Everett Fisheries case (cited in Appellants' Main Brief at p. 25 and reprinted in full in the Addendum thereto at A10), expressly accorded such status to an interpretive regulation under §701(a) of the Federal Food, Drug, and Cosmetic Act.

Appellees seek to read into the decision (Br. p. 15) in Abbott Laboratories v. Gardner, 387 U.S. 136 (1967) a holding that §701(a) interpretive regulations have the status of law thereby precluding a full factual judicial review. Appellees totally misread the decision in Abbott Laboratories. In that case, the FDA sought to prevent pre-enforcement judicial review of a §701(a) interpretive regulation on the grounds that, in accordance with prior practice, such a challenge could be made only as a defense to enforcement proceeding. The Court, however, allowed pre-enforcement judicial review because the threat of future enforcement presented a sufficient basis for the exercise of judicial review:

> "The alternative to compliance - continued use of material which they believe in good faith meets the statutory requirements, but which clearly does not meet the regulations of the Commissioner - may be even more costly.

> That course would risk serious criminal and civil penalties for unlawful distribution of 'misbranded drugs.'
> ...To require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily." Id. 387 U.S. at 153. */

In sum, Appellees' interpretation of Abbott Laboratories is the reverse of what was intended by the Court. Whereas the Court allowed pre-enforcement relief as a satisfactory alternative to challenge in an enforcement proceeding, Appellees would prohibit challenge in an enforcement proceeding and apparently allow only pre-enforcement challenge under the most limited scope of judicial review. Such an approach would frustrate the purpose of pre-enforcement relief. As noted in Abbott Laboratories:

> "[A] pre-enforcement challenge by nearly all prescription drug manufacturers is calculated to speed enforcement. If the Government prevails, a large part of the industry is bound by the decree; if the Government loses it can more quickly revise its regulations." Id. 387 U.S. at 154

It is apparent that the Court considered the parties involved to be "bound" only after and not before judicial review

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*/ It is for these very same reasons that Appellants have brought the instant case. It is therefore strange that Appellees (Br. p. 15) should seek to construe the industry's responsible course of action as a concession that the regulations are "binding."

was had. Abbott Laboratories cannot be read as denying Appellants' right to a trial with respect to a §701(a) regulation. Similarly, there is nothing in Abbott Laboratories which detracts from the long-established distinctions between interpretive and substantive regulations as borne out by the legislative history of §701(a).

Appellees' attempted distinction (Br. p. 19) of United States v. Everett Fisheries, 73 Cr. 109 (W.D. Wisc. May 30, 1973) is totally misplaced. First, the supposed distinction between "precise" and "imprecise" regulations is illogical and has no basis in any of the case law. */ Everett Fisheries involved 21 C.F.R. §128(a) which is in fact very precise. Said interpretive regulation deals specifically and expressly with the entire manufacturing process for smoked fish and smoke-flavored fish and, among other things, provides (1) for use of thermometer with an accuracy of $\pm$ 2° F. (128 a.4d), (2) that frozen fish be defrosted

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*/ Appellees' Brief (p. 19) erroneously cites Weinberger v. Hynson, Westcott & Dunning, Inc., 416 U.S. 609, 621 at n. 17, which merely mentioned that the agency's summary judgment rule could only be applied to deny a hearing under the new drug provisions of the Act where the regulation clearly sets forth the prior requirements for a hearing. This necessarily has no bearing on the general scope for review of other regulations.

Appellees also cite the same case as holding that §701(a) regulations are not subject to the "substantial evidence" test. (Appellees Br. p. 18). Once again, the indicated footnote at 412 U.S. 622 only states that review of an agency denial of hearing under the new drug provisions of (continued on page 22)

at 45° F. (128a.7b), (3) that fresh fish be refrigerated at 38° F. (128a.7a), and (4) that the fish containing 3.5% salt be processed at not less than 180° F. for a minimum of 30 minutes. [128a. 7(d)(2)(i)].

The Court expressly held with respect to this interpretive regulation that in an enforcement proceeding the manufacturer has a full right to dispute the specific requirements for the purpose of showing that fish processed otherwise were in fact not adulterated and that the interpretive regulation would be given only such weight as it deserved under the facts of the case. See Addendum to Appellants' Main Brief at A10.

It is in this respect too that Appellees' attempted distinction (Br. pp. 19-20) of Salazar v. Hardin, 314 F.Supp. 1257 (D. Col. 1970) points out the fundamental error in their approach. That case, as here, involved a declaratory challenge to an interpretive regulation. The Court gave "weight" to the agency interpretation but, because a full trial of the facts was had, the Court was able to strike down the regulation as contrary to the

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*/ (cont'd from p. 21)
the Act is not governed by the "substantial evidence" test but by the general principle applicable to summary judgment procedures. No reference is made at all to §701(a) regulations. Appellants do argue in the alternative that the "substantial evidence" standard should apply to §701(a) regulations. (See Appellants' Main Brief, pp. 46-51)

applicable statute.

The only case cited by Appellees for the proposition that a full trial may not be had in an enforcement proceeding, United States v. Bodine Produce Co., 206 F.Supp. 201 (D. Ariz., 1962), actually supports Appellants' position. That case did not involve an interpretive regulation but rather a substantive regulation pursuant to §701(e) of the Act which was preceded by a full hearing and the option of judicial review in a Court of Appeals under the substantial evidence standard. Thus, the Court held that "substantive" regulations were binding and could not be challenged in enforcement proceedings. The instant case, however, involves an interpretive Statement of Policy, preceded only by an expression of agency opinion as supposedly endorsed by "experts." The District Court, improperly refused to allow a trial as to such an interpretive regulation despite the long-standing judicial recognition of the distinction between interpretive and substantive regulations.

Finally, it should be noted that a holding that §701(a) regulations are only interpretive and subject to a full factual challenge in a district court will, in no way, impede the efficient enforcement of the Act. An interpretive regulation or Statement of Policy is issued for the purpose of advising the public as to the agency's position and to secure compliance.

Responsible members of the affected public will either comply or else seek declaratory relief as is being done in the instant case. Thus, the issuance of an interpretive regulation or statement of policy is an efficient mechanism for avoiding the need to proceed on a case-by-case basis while allowing litigants a full opportunity to present factual proofs upon a court challenge to the agency action.

A §701(a) Statement of Policy should not be used by the agency, however, to reduce its factual burden in establishing the validity of such policy. If, without such a Statement of Policy, an enforcement action had been commenced, seeking to seize vitamin A and D products from being sold without a prescription, the affected manufacturers could have disputed the agency's opinion by full factual proofs. The fact that the agency chooses to announce its opinion and interpretation in advance does not alter that basic right in enforcement proceedings. See United States v. Everett Fisheries, supra. Similarly, the same right should apply to pre-enforcement declaratory judgment actions which seek to prevent, and avoid the need for recourse to potentially harmful enforcement proceedings. It is respectfully submitted that the district court erred in refusing to allow a trial on the evidence below and that its decision should be reversed.

POINT IV

APPELLEES' BRIEF DEMONSTRATES THE INADEQUACY OF THE RECORD BELOW

Appellees' Brief, pages 5-6, makes reference to various medical articles for the purpose of showing the alleged factual propriety of the instant Statement of Policy. The essential problem in these proceedings has always been the gap which exists in the expressed agency reasoning between the alleged "high dosage" toxicity and the prescription levels imposed.

As noted in Appellants' Main Brief (pages 55-57), no references or analysis was made public by the agency to explain the 10,000 I.U. and 400 I.U. levels chosen. Somewhat cryptically, the Commissioner states and Appellees' Brief repeats that dosages of 50,000 I.U. of vitamin A in adults are "known" to produce toxicity (JA 36a) (Appellees' Brief, p. 4). With respect to vitamin D, the Commissioner made no statement at all as to any quantity which produced adverse results in adults. (See also JA 172a, 156a-157a).

The Comments submitted to the agency very strongly pointed out that on the basis of analysis of the medical literature, the agency's indicated ranges for possible adverse results were totally unsupportable. Every analysis of the literature submitted to the agency showed the few cases of vitamin A toxicity in adults were not manifested until there had been an ingestion of

generally over 200,000 I.U. over prolonged periods, sometimes ranging many years. Similar analyses were presented with respect to vitamin D (see, e.g., JA 44a-49a, JA 113a-115a, Ja 148a, JA 150a and JA 171a). These analyses were shown to be further supported by the testimony of witnesses at the vitamin hearings. (JA 72a-83a and JA 172a). In response to these detailed analyses, the Commissioner made only the following ambiguous response:

> "The Commissioner has carefully reviewed the comments and analysis regarding the medical/ scientific justification for establishing the proposed vitamin A and vitamin D limits and finds that such comments do not sufficiently support a revision of the proposed limits." (JA 33a)

At no time has the Commissioner ever explained the justification for the 10,000 I.U. and 400 I.U. levels in light of the analysis in the Comments showing the totally disproportionate astronomical ingestion required before any reported adverse results, particularly in adults. Appellees' Brief, however, seeks to make some specific reference to the articles as a substitute for such an analysis by the Commissioner. */ These citations alone demonstrate the enormity of the gap in the Commissioner's reasoning. The cited cases involving teenagers dealt with the ingestion of 200,000 units of vitamin A for periods of more than 10 months and

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*/ See also discussion of the unacceptability of post hoc rationalization by counsel. Supra, pp. 6-7

two years respectively (E258, E275 and E363) */; the 38-year old woman (E299-303) who had a case of hypervitaminosis A had been taking 15 tablets a day for a total of 375,000 I.U. per day, and finally the cited 41-year old judge had been taking 200,000 units of vitamin A each day for a period of 12 years in accordance with a prescription of a physician. (E552-556). It is significant that the cases cited to this court by Appellees' counsel tend to confirm the analyses submitted in the Comments and the position taken by Appellants herein

More recently, Appellants have learned of a specific agency analysis of the vitamin A literature showing possible adverse effects in single doses of Two Million I.U. This analysis further deals with chronic ingestion in relationship to body weight of the person concerned. This analysis is found in a letter dated October 4, 1973 in which the agency advises that:

> "Continuous daily doses of 4,000 to 25,000 I.U. per kilogram of body weight for a period of 6 to 15 months have been known to produce chronic toxicity." (emphasis added)

A copy of this FDA letter is annexed hereto in the Supplemental

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*/ Much of the literature is repetitious and duplicates reports of identical individual cases. These articles in their present form most certainly fall far short of even the minimum requirement that the agency imposes for submission by industry.

Addendum at SA1.

According to this letter dated only three days after the instant Statement of Policy went into effect, the range for adverse results for a 150 pound adult would be the ingestion of approximately 272,000 to 1,700,000 I.U. of vitamin A each day over a period of 6 to 15 months. Surely, Appellees cannot successfully contend that where adverse results are noted in such astronomical quantities that a prescription limitation can properly be set at the low levels of 10,000 I.U. and 400 I.U. respectively.

Once again, however, it must be reiterated that this entire discussion does not reach the basic requirement under the prescription statute of showing a necessity of supervision by a physician for vitamin A and D products in excess of the 10,000 I.U. and 400 I.U. respectively.

The above merely serves to highlight the inadequacy of the record below. Without a trial or at least some form of compelling additional information from the agency (such as by way of deposition), there is no basis for the instant prescription levels other than the agency's "opinion" accompanied by simple letter endorsements which in part assume the validity of the very opinion that they are endorsing.

As noted in Appellees' Main Brief (p. 57), both the

original and final agency action herein were preceded by ex parte discussions between the Commissioner and unidentified medical experts. In addition to rendering the record deficient in accordance with the "whole record" requirements of the Administrative Procedure Act, such informal and non-record reliance on outside advisors in connection with the promulgation of regulations is also a violation of the Federal Advisory Committee Act, 5 U.S.C. App. I, which requires that such advisory functions be accompanied by full public disclosure. See, e.g., 5 U.S.C. App. I §10. See Food & Chemical News, Inc. v. Davis, 378 F.Supp. 1048 (D.D.C. 1974) holding that the Federal Advisory Committee Act prohibits undisclosed advisory functions with respect to agency preparation and promulgation of regulations even where there is no formal advisory group established.

Many other factors in the instant case demonstrate the factual insufficiencies of the record. For example, Appellees' Brief (p. 29) suggests that the availability of vitamin A in the food supply increases the danger of illness from additional amounts taken in pill form, while a footnote on the same page points out that vitamin A found in foods does not cause toxicity. Similarly, the record suggests that natural vitamin D is not toxic (JA 74a) while the Commissioner simply asserts that there are no distinctions

to be made for natural vitamin products (JA 32a). See also Appellees' Brief, pages 56-58, and Comments submitted to the agency (JA 109a-179a). The record which the agency filed with the court is totally insufficient to explain how the prescription levels herein were established. Appellees' citation (Brief p. 21) of Consumers Union of United States, Inc. v. Consumer Product Safety Commission, 491 F.2d 810 (2d Cir. 1974) is misplaced. The quoted language from that case seems to suggest that evidence in an agency's files need not be placed in the record before the court. Actually, in the Consumers Union case the record before this court did include the entire agency file, including every step in the administrative decision-making process leading up to the regulations in question. A copy of the index to the certified record on appeal and the supplementary index taken from the office of the Clerk of this Court, is annexed hereto in the Supplemental Addendum at SA 2. */ The reference by the court apparently is that while the evidence

*/ A copy of these materials was also submitted to the District Court. It should, of course, be noted that the Consumers Union case is inapposite in terms of the question as to Appellants' right to a trial herein. That case involved review upon a petition to the Court of Appeals on a statutory record. It is not clear, however, why the Court applied the arbitrary and capricious standard when the applicable statute, 15 U.S.C. §1262(e)(3)(C), expressly makes the "substantial evidence" test applicable.

need not completely be in the Comments submitted to the agency it could be found in the balance of the Commission's files, all of which was presented to the court. In the instant case, however, the agency has filed only the Comments and the lower court denied Appellants' request to conduct discovery so as to compile the "whole record" which figured in the agency determination.

Unless either a full trial is had in the court below or sufficient discovery is allowed, as discussed above, the full factual basis for the regulations and their indicated factual infirmity cannot be fully presented. As it stands, the record, by reason of the above, necessarily characterizes the instant Statement of Policy as unsupported by substantial evidence and as arbitrary and capricious. The error of the District Court lies in the failure to allow a sufficient inquiry which would have required the agency to fully explicate its analysis, reasoning and factual support.

CONCLUSION

For the reasons stated in this Reply Brief and Appellants' Main Brief, it is respectfully submitted that the decision of the lower court should be reversed and that the instant Statement of Policy should be ruled invalid.

Respectfully submitted,

BASS & ULLMAN
Attorneys for Plaintiffs-
Appellants

Supplemental Addendum SA 1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

October 4, 1973

Mr. Walter Ermer
International Health Council
15328 Edolyn Avenue
Clevelan Ohio 44111

Dear Mr. Ermer:

This is in reply to your letter of August 15, 1973, regarding hypervitaminosis A.

The enclosed reprint from the Federal Register of August 2, 1973 gives our position on the status of vitamin A at page 20723 ff.

To respond to your specific questions, a single dose of over 2,000,000 I.U. of vitamin A can produce an increase in cranial pressure when administered to an adult, and a dose of over 350,000 I.U. can cause the same effect in an infant. Such symptoms are reversible. Continuous daily doses of 4,000-25,000 I.U. per kilogram of body weight for a period of six to fifteen months have been known to produce chronic toxicity.

Information regarding hypervitaminosis A and chronic toxicity due to vitamin A has been gathered from the literature. A copy of a bibliography is enclosed. Texts such as "The Pharmacological Basis of Therapeutics" edited by Louis S. Goodman and Alfred Gilman (4th edition, 1970) provide summaries of knowledge on the subject.

We are not aware of any tests on humans to determine the levels of vitamin A which would produce damage. The implicit hazards preclude such experimentation. Our information on toxic levels has come from reports of accidental ingestion of large amounts and of deliberate, long-term ingestion of high dosages.

Sincerely yours,

Jack Kaye, Chief
Advisory Communications Branch
Bureau of Drugs
BD-49

Enclosures

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CONSUMERS UNION OF UNITED STATES, INC., Petitioner	)	
v.	)	No. 73-1617
CONSUMER PRODUCT SAFETY COMMISSION, Respondent.	)	

CERTIFIED LIST OF RECORD PURSUANT TO RULE 17(b) OF THE FEDERAL RULES OF APPELLATE PROCEDURE

I hereby certify that the following material listed comprised the record upon which judicial review is sought:

1. Report titled "Position Paper on Grounding of Appliances and Electrical Systems" prepared for the National Commission on Product Safety and dated June 16, 1969.

2. Memorandum of a telephone conversation between Dr. Duan L. Larson and Mr. Dale C. Miller and dated April 17, 1970.

3. Memorandum of a telephone conversation between Colonel Basel Pruitt and Mr. Dale C. Miller and dated April 20, 1970.

4. Memorandum of a meeting prepared by Mr. Richard D. Burly and dated May 6, 1970.

5. Paper titled "Report of Test on Toy Electric Drills" by Samuel D. Toner and dated December 2, 1970.

6. Letter, with attachments, from Aaron Locker to Mack Jensen dated February 5, 1971.

7. Underwriters' Laboratories, Inc., proposed revision of the Standard for Electric Toys (UL696-1966) dated June 29, 1970.

8. Underwriters' Laboratories, Inc., proposed revision of the Standard for Electric Toys (UL696-1966) dated January 11, 1971.

9. Paper titled "TMA Proposed Regs".

10. Memorandum from Donald F. McCaulley to D. C. Miller on the subject of the T.M.A. Proposed Standard-Electrical and Thermal Toys and dated February 18, 1971.

11. Report dated March 18, 1971, containing comments on proposed regulations for thermal and electric toys from the National Bureau of Standards.

12. Draft of Proposed Regulations for Electrical and Electro-Thermal Toys prepared by D. L. Gordon and dated March 18, 1971.

13. Report titled "Thermal Limitations for Toy Safety" prepared by Yung-Chi Wu and dated March 24, 1971, including reference material.

14. National Bureau or Standards report titled "Toy Metal Casting Sets: Evaluation of Electrical and Thermal Characteristics" dated April 27, 1971, and transmittal letter dated May 3, 1971.

15. Underwriters' Laboratories, Inc. Standard for Safety-Electric Toys (UL696) dated July 1, 1971.

16. Paper titled "Material Properties Criteria for Thermal Safety" by Y. C. Wu and transmittal slip dated December 3, 1971.

17. National Bureau of Standards report titled "Temperature Profiles of Selected Thermal Toys" and transmittal letter dated December 14, 1971.

18. One study entitled "Child Development and Personality", Third Edition, 1969, by Mussen, Conger, and Kagon, published by Harper and Row, Library of Congress catalog Card Number 69-14984.

19. One file labeled "Drafts of Elec. Toy Proposal" consisting of the following:

a. Proposal labeled "First Draft";

b. Proposal labeled "Second Draft" and dated 6-25-71;

c. Paper marked "Changes to 7/22/71 draft developed 7/23";

d. Proposal and "Action Memorandum" dated July 23, 1971;

e. Edited proposal and transmittal memoranda variously dated from September 2, 1971, to December 9, 1971; and

f. Revised Proposal and transmittal memorandum dated January 11, 1972.

20. Federal Register notice proposing the banning of certain electrically operated toys and children's articles, 37 Fed. Reg. 1020 et seq.

21. One file labeled "§191&§191(b) - Proposed Classification - Certain Electrically Operated Toys and Other Electrically Operated Children Articles as Banned Hazardous Substances", containing comments collected in the Office of the Hearing Clerk.

22. One file labeled "Drafts of Elec. Toy Order" consisting of the following.

a. Document stamped "Working Draft, Nov. 1972"; and

b. Draft order dated January 18, 1973, with transmittal memorandum dated January 18, 1973, and referenced attachments.

23. Federal Register order banning certain electrically operated toys and other electrically operated children's articles, 38 Fed. Reg. 6138 et seq.

Samuel M. Hart

SAMUEL M. HART
Acting Secretary
Consumer Product Safety Commission

June 8, 1973

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CONSUMERS UNION OF UNITED STATES, INC., Petitioner	)	
v.	)	No. 73-1617
CONSUMER PRODUCT SAFETY COMMISSION, Respondent	)	

JOINT MOTION TO SUPPLEMENT
CERTIFIED LIST OF RECORD

Petitioner and respondent jointly move this court to supplement the certified list of record in the above-entitled case.

Because of the transfer of authority for the administration of the Federal Hazardous Substances Act, under which the instant case is brought, from the Food and Drug Administration to the Consumer Product Safety Commission, pursuant to 15 U.S.C. 2179(a), all materials which might have been certified as part of the record on appeal were not adequately considered in time for certification of the record by respondent. Therefore, petitioner and respondent jointly move this court to allow the enlargment of the certified record, by addition of the items listed below.

1. Memorandum dated February 8, 1971, from Dale C. Miller, Office of Compliance, to the Director of the Bureau of Product Safety, FDA, re toy standard of the Toy Manufacturers of America.

2. Maximum temperature charts from the draft of UL696, Underwriters' Laboratories Standard for Electric Toys.

3. Draft of proposed regulations, dated March 18, 1971, marked, "D.L. Gordon".

4. Undated draft of proposed regulations.

5. Undated draft of proposed regulations with unidentified pencilled comments.

6. Comments by Sam Hart on proposed regulations (pencilled on yellow legal sheets).

7. Undated carbon copy draft of proposed regulations with unidentified orange pencilled comments.

8. Reprint from Journal of Materials, Vol. 7, No. 4, December 1972, pp. 573-9, of article by Yung-Chi Wu, entitled "Material Properties Criteria for Thermal Safety."

9. Xerox copy of handwritten comments entitled, "Some Individual Comments from Toy Safety Group Members Concerning Standards for Electrically Operated Toys", dated June 21, 1971.

10. Undated draft of proposed regulations with handwritten comment on first page concerning "meeting here next Thursday."

11. Undated draft of maximum acceptable surface temperatures chart from proposed regulations, with penned changes.

12. Draft of proposed preamble and proposed final regulations with pencilled changes.

Respectfully submitted,

Peter H. Schuck

Marsha N. Cohen

Attorneys for Petitioner

Consumers Union of United States, Inc.
1714 Massachusetts Avenue, N.W.
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Thomas E. Kauper
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Michael A. Brown

Paul W. Hallman

Consumer Product Safety Commission
Washington, D.C. 20207

July 20, 1973

So Ordered:

Date: July 27, 1973

A. Daniel Fusaro
Clerk

By: Vincent A Carlin

Vincent A. Carlin,
Chief Deputy Clerk

A 202 Affidavit of Personal Service of Papers LUTZ APPELLATE PRINTERS INC.

US COURT OF APPEALS: SECOND CIRCUIT

Index No.

NAT'L NUTRITION,
Plaintiffs-Appellants,

against

WEINBERGER,
Defendants-Appellees,

Affidavit of Personal Service

STATE OF NEW YORK, COUNTY OF NEW YORK ss.:

I, James Steele, being duly sworn,

deposes and says that deponent is not a party to the action, is over 18 years of age and resides at

250 West 146th Street, New York, New York

That on the 24th day of October 1974 at Foley Sqaare, New York

deponent served the annexed Reply Brief upon

Paul J. Curran

the in this action by delivering 2 true copies thereof to said individual personally. Deponent knew the person so served to be the person mentioned and described in said papers as the Attorney(s) herein,

James Steele

Print name beneath signature

JAMES STEELE

Sworn to before me, this 24th

day of October 1974

Robert T. Brin

ROBERT T. BRIN
NOTARY PUBLIC, STATE OF NEW YORK
NO. 31 - 0413950
QUALIFIED IN NEW YORK COUNTY
COMMISSION EXPIRES MARCH 30, 1975